FDA PUBLIC MEETING ON SAFETY ISSUES ASSOCIATED WITH DIETARY SUPPLEMENT USE DURING PREGNANCY – MARCH 30, 2000

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My name is Josef Brinckmann. I am the Research and Development Manager for Traditional Medicinals, Inc. of Sebastopol, California, a manufacturer of Herbal Dietary Supplement products for preparation in the traditional aqueous infusion dosage form. Many of our products have also been registered for over 15 years within the Traditional Herbal Medicine (THM) class of drugs in Canada by the Health Canada Therapeutic Products Programme. As a preface to my comments, I would like to state that I have a 20-year-old daughter who was born at home and that we are expecting another daughter in May of 2000. It is relevant to state that my own family relies mainly on Traditional Herbal Medicine, particularly as prescribed from licensed acupuncturists (L.Ac.) trained in Traditional Chinese Herbal Medicine (TCHM), for our primary health care needs. My wife is also currently under the pre-natal care of a certified nurse-midwife (CNM) who recommends and/or dispenses certain commercially available herbal dietary supplement products for common pregnancy related conditions. My wife has been using certain appropriate herbal dietary supplements in herbal tea, tincture, and fluidextract forms, throughout her pregnancy with satisfactory effect.

For over 25 years, our company has provided a range of traditional women's herbal formulas, including pregnancy and lactation products. Our herbal dietary supplement products are widely recommended by licensed health care professionals who have direct experience in pre- and peri-natal care including registered nurses (RN), certified nurse-midwives (CNM), certified professional midwives (CPM), licensed midwives (LM), certified childbirth educators (CCE), certified lactation educators (CLE), certified doulas (CD), and naturopathic physicians (ND). Our women's herbal products are in fact served in hospital maternity wards and community health centers and clinics. Advice with regard to retail stores where our products can be purchased is also given to patients by pre- and peri-natal consultants working in hospitals and women's health centers. It is important that our ability to communicate appropriate indications for use for these dietary supplement products, with the licensed practitioners and patients who rely on them, is not interrupted. Based on sales statistics, approximately 1,366,300 individual servings of our Pregnancy Tea, which has been on the market for 25 years, are ingested annually. In the last six years, only two non-serious adverse events have been reported to our customer service department for this product. These statistics demonstrate significant evidence of human safety.

With that being said, there are a number of manufacturers of ethical herbal products who share some of the serious concerns that are being raised in this public meeting and we wish to be distinguished from the manufacturers of non-traditional, modern and/or novel

phytopharmaceutical dietary supplement products that may be marketed to pregnant women under the provisions of DSHEA though they can not demonstrate a long extent of safe use among pregnant women. There needs to be a clear differentiation made between modern, non-traditional products with no safety record from those herbal products that have been used traditionally, and continue to be used successfully, by a significant population of pregnant women for common, non-serious conditions related to supporting a healthy pregnancy. Our recommendation is that such differentiation can be determined by an expert panel composed of our colleagues who are trained in the herbal medical arts and sciences such as Licensed Acupuncturists (L.Ac.) and Naturopathic Physicians (ND) as well as practicing Members of the National Institute of Medical Herbalists (MNIMH) of Great Britain and medical doctors (MD) from European countries such as France and Germany, where traditional phytomedicine remains an integral part of their curriculum and within their scope of practice. We believe that responsibly formulated traditional herbal products, manufactured under Good Manufacturing Practice (GMP) conditions, from companies who have produced the requisite substantiation files in support of an allowable structure/function statement and have had those files reviewed by a qualified expert, should be allowed to market their products to the women who rely on them, and to communicate the products' specific indications for use during pregnancy. Licensed practitioners rely on the availability of these dietary supplement products in local pharmacies and/or natural foods markets if their clinics do not have an associated herbal dispensary.

I'll now point to just a few specific examples though there are many. In 1999, the World Health Organization (WHO) reported that the medicinal use of Ginger preparations to treat pernicious vomiting in pregnancy is supported by clinical data (WHO, 1999). Naturopathic physicians report that mild nausea as well as hyperemesis gravidarum are effectively treated with Ginger (Yarnell, 1997). According to the British Herbal Medicine Association (BHMA), which represents practicing medical herbalists and pharmacists, Ginger preparations are specifically indicated for vomiting of pregnancy (Bradley, 1992). In a double-blind randomized cross-over clinical trial Ginger effectively treated pernicious vomiting in pregnancy. No teratogenic aberrations were observed in infants born during the study, and all newborn babies had Apgar scores of 9 or 10 after 5 minutes (Fischer-Rasmussen et al. 1991). The Apgar score is an evaluation of a newborn's physical status by assigning numerical values. A score of 8 to 10 indicates the best possible score (Spraycar et al., 1995).

Another common example is the use of Raspberry leaf (*Rubus idaeus*) tea during pregnancy. According to the British Herbal Medicine Association (BHMA), Raspberry leaf is used as a partus-preparator (BHP, 1996). It has been used consistently in Europe since ancient times for nourishment during pregnancy and preparation for delivery (Bergner, 1997; Gladstar, 1993). In a recent national survey of herbal preparation use by Certified Nurse-Midwives (CNM), 63% of the respondents who use herbal preparations in their practice reported recommending Raspberry leaf. Raspberry leaf tea is traditionally used during pregnancy for morning sickness, to prevent miscarriage, and to shorten and ease labor (McFarlin et al., 1999). In North American and European systems of medical herbalism, Raspberry leaf has a long tradition of use in pregnancy to

strengthen and tone the tissue of the womb, assist contractions and check any haemorrhage during labour (Bergner, 1997; Gladstar, 1993; Hoffmann, 1990). Additionally, in North American aboriginal medicine, Raspberry leaf tea has a long history of human use as a birthing aid to treat labor pains, particularly among the Cherokee, Chippewa, Iroquois and Mohawk nations (Bergner, 1997; Moerman, 1998). In 1999, professor of pharmacognosy Dr. Varro Tyler wrote that while he believes there is insufficient scientific evidence of benefit at the present time, if pregnant women believe that Raspberry leaf tea provides relief from various unpleasant effects associated with their condition, no harm is done (Foster and Tyler, 1999).

In the Traditional Chinese Medicine (TCM) system of herbalism, traditional herbal formulas that are appropriate for use during pregnancy, for example to prevent miscarriage, to treat non-severe cramping pain in the abdomen, slight edema of the lower limbs, or for treatment of morning sickness, are clearly differentiated in the formularies and/or materia medica from those formulas that may be used only with caution during pregnancy and from those formulas that are specifically contraindicated during pregnancy, based on a multi-thousand year history of clinical use among a large portion of the world's population (Bensky and Barolet, 1990). Though pregnant women should first seek the advice of an L.Ac., specializing in gynecology, before using certain TCM products (Taylor, 1998), the availability and accurate labelling of such traditional herbal dietary supplement products is important to the practitioners and their patients who rely on them for health care during pregnancy.

In closing, I want to reiterate that the concerns are certainly valid and therefore a distinction must be made between those herbal dietary supplements that have a long history of use, and are currently used within the medical system, vs. any new or novel products that do not have sufficient evidence of safe use by pregnant women over a significant extent of time. I'd like to thank the FDA for creating this forum and allowing me the opportunity to address the panel on the long history of safe use of certain appropriate traditional herbal dietary supplements during pregnancy.

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